Compliance Programs: The Next Generation

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Objectives

- What does “effective” mean?
- Compliance Metrics in 2013
- Do you know how to audit?
- What to do if an “overpayment” is identified?
Effectiveness Measures

✓ Structure
✓ Process
✓ Outcome

Linkages between structure, process and outcome measures are important.

Elements of a Compliance Program and Phases of Implementation

Phase I: Authorization / Leadership
Phase II: Standards/Code of Conduct
Phase III: Compliance Policies and Procedures
  - Infrastructure
  - Operational
Phase IV: General Training Program
Phase V: Specialized Training Program
Phase VI: Reporting Mechanism
Phase VII: Monitoring and Auditing
Phase VIII: Response and Prevention
Phase IX: Enforcement and Discipline
Phase I: Authorization / Leadership

Example:

Structure:
- Senior leaders members of a Compliance Committee

Process:
- Appropriate documentation of compliance committee activity, with focus on specific program elements

Outcome:
- Overall attendance at compliance committee meetings consistently greater than 75%

Phase II: Standards/Code of Conduct

Example:

Structure:
- Create/Review Standards/Code of Conduct

Process:
- Distribute Standards/Code of Conduct
  - Employees and Agents

Outcome:
- Employee understanding of the Standards/Code of Conduct
- Distribution has been tracked and attestations retained, expect 100% completion
Phase III: Policies and Procedures

Structure:
- Policies and procedures are clearly written and relevant to day-to-day responsibilities.

Process:
- Policies and procedures are readily available to those who need them on a well indexed and searchable Intranet.

Outcome:
- Adherence demonstrated in monitoring/auditing/observations
- Employee Survey Results
  - Surveyed employees feel policies and procedures assist them in doing their job effectively.

Phase III: Policies and Procedures

- Compliance Program Infrastructure

- Operational (Risk Areas)
Background Screening

Structure:
- Policies and procedures and expectations clear and meet regulatory expectations

Process:
- Specific to meet federal and state expectations, and expectations of center/company
- At minimum preliminary screening includes licensure/references/sanction lists (LEIE & GSA) prior to hire
- Includes quality controls
- Includes specific tracking mechanisms

Outcome:
- 100% of employees complete screening

Phase IV: General Training Programs

Example:

Structure:
- Compliance Training Materials

Process:
- Training process (on-line, instructor-led, video, self-study, etc.)

Outcome:
- Tracking training completion
Phase IV: General Training Programs

- General/Annual Compliance Training includes Standards of Conduct
- New Employee Orientation

Phase V: Specialized Compliance Training Programs

Example:

Structure:
- Develop specialized compliance training for high risk areas within targeted departments

Process:
- Training process (on-line, instructor-led, video, self-study, etc.)

Outcome:
- Tracking specialized compliance training completion
Phase V: Specialized Compliance Training Programs

- Supervisor/Manager Training
  - Treating each question/report confidentially
  - Non-retaliation against any employee asking a question or making a report
  - Documenting and tracking such questions/reports
  - Knowing when to refer the incident to the compliance officer

Phase VI: Reporting Mechanism

Example:

Structure:
- Anonymous Hotline Established

Process:
- Hotline well-publicized in Standards of Conduct, posters, magnets, on employee badges, pens, mouse pads, etc.

Outcome:
- Awareness of hotline (employee survey results)
Phase VI: Reporting Mechanism

Open communication is essential to maintaining an effective compliance program. The purpose of developing open communication is to increase the skilled nursing facilities' ability to identify and respond to compliance problems.

Generally, open communication is a product of organizational culture and internal mechanisms for reporting instances of potential fraud and abuse.
Phase VI: Reporting Mechanism

Report Sample

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<th>Location</th>
<th>Time Period</th>
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<tr>
<td>Inquiries by Overall Category</td>
<td>1Q 2011</td>
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<tr>
<td>Billing</td>
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<tr>
<td>Facility Practice</td>
<td>1</td>
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<td>Human Resources</td>
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<td>Staffing</td>
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Phase VII: Monitoring and Auditing

- Risk Assessment

The purpose of the risk assessment process is to identify and assess areas of regulatory compliance risks the organization encounters in order to prioritize audits and/or establish additional controls.
Phase VII: Monitoring and Auditing

- Risk Assessment

Sources for Risk Universe – Focus upon generally higher risk areas for error already identified by the Department of Health & Human Services (DHHS) Office of Inspector General (OIG) and Center for Medicare & Medicaid Services (CMS)

Example:

Structure:
- Annual Work Plan Created (with specific monitoring activities)
- Annual Auditing Plan Created

Process:
- Conduct Monitoring Activities
- Conduct Audits

Outcome:
- Monitoring Results
- Dashboard to Board or Compliance Committee
- Audit Results
Compliance Plan, Work Plan and Audit Plan

**Compliance Plan** - this is a description of the compliance infrastructure and how the program will operate.

**Compliance Work Plan** - this is a document which clearly articulates the annual goals and monitoring initiatives of the compliance program.

**Compliance Audit Plan** - this is a document that clearly articulates the compliance audits that will be performed for the year.

Phase VIII: Response and Prevention

*Example:*

**Structure:**
- Proper response team created

**Process:**
- Prompt and thorough investigation
- Root Cause Analysis conducted
- Corrective Action Plan created

**Outcome:**
- Corrective Action completed
Phase IX: Enforcement and Discipline

Example:

Structure:
- Disciplinary standards

Process:
- Thorough documentation of enforcement of disciplinary standards

Outcome:
- Disciplinary standards are consistently enforced
- Tested/Reported through specific incidents and Compliance Committee Actions

Measuring Compliance Culture – Employee Surveys

Outcome Measures:

What do we really want to know/prove?
- Do employees believe this is an ethical organization that is committed to complying with the laws, rules and regulations that govern its operations?

- Do employees know the organization has a Compliance Officer?
Measuring Compliance Culture
– Employee Surveys

Outcome Measures:

➢ Is the training that employees receive sufficient to address compliance requirement for their job?

➢ Do employees feel that management and/or the compliance officer follow-up on reports of compliance concerns and take appropriate action whenever necessary?

Measuring Compliance Culture
– Employee Surveys

Outcome Measures:

➢ Do employees know how to report compliance concerns?

➢ Do employees feel they can freely report ethics and compliance issues without fear of retaliation from managers?
Compliance Metrics
2013

Effective Measures for Each Element

- Creation of Dashboard
  - Inclusion/coordination with other operational reporting

- Reporting Structure
  - Transparency and Availability
  - Review with Key Leadership

- Usage of Data
  - Education/Training Metrics
  - Disclosures Data
  - Monitoring Scores
### Sample Dashboard

**Location**
- Compliance Leader
- Prepared By: Compliance Department/Compliance Director

**As of Date**
- Q3 2011
- Q2 2011
- Q1 2011
- Q4 2010

#### Leadership

<table>
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<tr>
<th>Compliance Element Outliers</th>
<th>Education</th>
<th>Education</th>
<th>Background Screening Prior to Hire</th>
<th>Peer(s)</th>
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<tr>
<td>% Compliance Liaison Reports Completed</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
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<tr>
<td>% Background Screening Prior to Hire</td>
<td>96%</td>
<td>98%</td>
<td>87%</td>
<td>87%</td>
</tr>
<tr>
<td>% Peer(s)</td>
<td>98%</td>
<td>96%</td>
<td>97%</td>
<td>99%</td>
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#### Code of Conduct/Policies and Procedures

| % Compliance of Allegations - Employee | 100% | 100% | 100% | 100% |
| % Completion of Allegations - Physicians | 78% | 78% | 50% | 45% |
| % P & P Adoption and Sign Off | 98% | 98% | 91% | 99% |

#### Background Screening

| % OIG/DOJ Prior to Hire | 100% | 100% | 100% | 100% |
| % OIG/DOJ Monthly | 100% | 100% | 100% | 100% |
| % Screening Completed Prior to Hire | 97% | 96% | 87% | 89% |
| % Open Screenings/Requires Additional Documentation | 2% | 3% | 12% | 2% |

### Sample Dashboard

**Education**

| % Code of Conduct Training Completed with 30 days of hire | 98% | 90% | 96% | 94% |
| % Completion of HIPAA Training | 65% | 70% | 76% | 87% |
| % Completion of Specific Training | 78% | 70% | 74% | 72% |
| Annual Re-training | 98% |

**Disclosures Program**

| SQL Count | 40 | 25 | 59 | 43 |
| CFL Count | 30 | 26 | 24 | 22 |
| Direct Inquiry Count | 13 | 14 | 21 | 16 |
| **SUBTOTAL** | 92 | 65 | 104 | 81 |
| Annual Surveys | 17 | 37 | 12 | 3 |
| **TOTAL** | 109 | 102 | 118 | 84 |

| Average Days to Call Closure | 13 | 18 | 23 | 17 |
| Substantiated Count | 11 | 22 | 7 | 8 |
| Partially Substantiated | 13 | 21 | 31 | 10 |
| Unsubstantiated Count | 45 | 58 | 34 | 46 |
| Pending | 27 | 2 | 2 | 2 |

**Top Three Concerns**

| Inappropriate Patient Care | 27 | Inappropriate Patient Care | 49 | Dissatisfaction w/Supervisor | 25 | Dissatisfaction w/Superior | 17 |
| Administrative Management | 16 | Administrative Management | 20 | Administrative Management | 15 | Administrative Management | 12 |
| Dissatisfaction w/supervisor | 16 | Patient Rights | 13 | Inappropriate Patient Care | 15 | Patient Rights | 6 |
Sample Dashboard

**Monitoring/Auditing**
- Quality Monitoring Average Score
- MDS Audit Average Error Rate
- Reported Overpayments %
- State Survey Average # Deficiencies
- HCP

<table>
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<tr>
<th>Outlier Centers</th>
<th>Reason (Frequency/Severity)</th>
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<td>South Dakota</td>
<td>Explanation</td>
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<tr>
<td>Georgia</td>
<td>Explanation</td>
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**Systemic Issues/Repeat Inquiries**

**Comments/Suggested Action Items**

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Do you know how to Audit?
Compliance Program Outcomes

- Two broad expectations
  - Reduction of fraud
  - Improvement in overall quality of care

- Results in:
  - Cost savings to government and center/company
  - Overall satisfaction with services

Quality Audit / Operational Audit

- Sample Selection
  - Random vs. Risk-based Selection: Locations, Controls and Residents
  - Independence/Objectivity
  - Expertise
  - Inter-rater Reliability
  - Protocols and Tools
  - Tests: Documentation / Observation / Interview
Quality Audit / Operational Audit

- Risk Assessment – What to Test?
- SNF Focus Areas – OIG Work Plan 2013
  - Services in accordance with RAI/Care Plans, Psychosocial needs
  - Rehospitalization, Rates of Adverse Events
  - Adverse Events
  - Verification of Deficiency Corrections
  - Use of Atypical Antipsychotic Drugs
  - Poorly Performing Nursing Homes
  - Accuracy of the MDS

Quality Audit / Operational Audit

- Phase VIII: Response and Prevention
  - Follow up to Audit

- Performance Improvement
  - Validation of Corrective Actions
  - Validation of Effect of Corrective Actions

- Adjustment to Audit Protocols
  - Feedback
  - Determination of Effectiveness
RUGs Audit

- Regulatory Overview
- Review Process
  - Selecting audit sample
  - Medical Necessity
  - MDS Review
  - RUG Calculation
- Common Areas of Concern

Regulatory Overview

- Medicare reimburses skilled nursing facilities based on Resource Utilization Group (RUG)
- Skilled Nursing Facilities are reimbursed a per diem rate based on RUG classification level
- RUG classification levels are based on the resources needed to provide the care
- 8 major classification levels
  - 66 Total sublevels
Regulatory Overview

- Classification levels based on MDS data
  - Only a subset of all data (90 data elements) collected on MDS can affect RUG classification level

- RUG classification levels are calculated starting at highest category and move progressively down until criteria for that level is fully met

Regulatory Overview

- 2 highest RUG classification categories, Category I and Category II (Rehabilitation Plus Extensive Services and Rehabilitation), require the provision one or more therapies (speech, physical and/or occupational)
Regulatory Overview

- If resident receives one or more therapies, only 2 sections from MDS affect RUG classification:
  - Section G—activities of daily living
  - Section O—calculates number of days and minutes of therapy provided

- Section G matters for all other Categories

- Other Sections affect other Categories

Regulatory Overview

- Medicare reimburses at specified intervals
  - 5, 14, 30, 60 and 90 day “assessment periods”
  - Each assessment period reflects the resident’s clinical status and resource need

- Each assessment period has an established Assessment Reference Date (“ADR”)

- Some MDS data elements have established “look back” period from the ADRs

- Some look back periods end being crucial for purposes of calculating classification levels
Selecting an Audit Sample

- By Patient
  - Audit each assessment period

- By Claim

Medical Necessity Review

- Technical Eligibility Requirements
  - Part A Eligibility
  - Qualifying 3 Day Inpatient Stay

- Clinical Eligibility Requirements
  - Services can only be performed in a skilled nursing facility
  - Resident requires skilled nursing on a daily basis
  - Services provided at skilled nursing facility are for a condition present in during the inpatient stay

- Physician Certification
  - Initial certification and recertification
MDS Review

- Review MDS against documentation in medical record and validate claim

- Section G and O are the most important sections for most assessment periods reviewed
  - Section G collects 2 sets of data (‘self-performance’ and ‘support’) on 10 different activities of daily living
    - Only 4 impact the RUG classification level
    - Support and self-performance calculated differently
  - Section O captures number of days and minutes of for each therapy provided

- Review other MDS elements for accuracy

RUGs Calculation

- Use calculation worksheet provided in Chapter 6 of CMS’s RAI Version 3.0 Manual

- Provides step by step process for manually calculate
Common Findings

- Lack of documentation to demonstrate Medicare eligibility
- Questionable 3 day inpatient stay
- Lack of signed or timely physician certification/recertification for skilled care and therapies
- Inconsistent ADL scoring
- Inconsistent or lack of documentation supporting therapy days and minutes
- Medical record failed to support coded data elements in MDS (e.g. diagnosis or treatment)

Consolidated Billing Audit

- Review UB04 and Verify:
  - Supplies
  - Pharmacy
  - Laboratory
  - X-Ray
  - Rehabilitation Services
    - Physical Therapy Units
    - Occupational Therapy Units
    - Speech Therapy Units
What to do with Audit Results?

Overpayments

- When To Get Legal Counsel Involved?

- Depends upon what the audit is finding or has found:
  - Implications of Fraud?
  - Excluded provider or entity?
  - Simple overpayment?
Overpayments

- Three Sources of Liability:
  1. Overpayment Liability Under the ACA
  2. Civil Monetary Penalty and Exclusion Liability
  3. False Claims Liability

- Type of Overpayment will Dictate Your Method of Reporting

"Simple" Overpayments

- Section 6402(a) of the ACA (42 U.S.C. sec. 1320(a)-7k(d)) provides that:
  - if a person has received an overpayment,
  - the person shall report and return the overpayment,
  - by the later of:
    - 60 days after the date on which the overpayment was identified; or
    - The date any corresponding cost report is due
“Simple” Overpayments

➢ Retention of an overpayment after this deadline is considered an “obligation” under the Federal False Claims Act.

➢ On February 16, 2012, CMS published a notice of proposed rulemaking addressing the “overpayment” provisions of the ACA. (77 Fed. Reg. 9179)

➢ Rule has yet to be finalized, but we can take some guidance from the notice of proposed rulemaking.

➢ Under the Notice of Proposed Rule Making:
  ➢ “Person” is defined broadly.
  ➢ “Overpayment” means any funds to which the person is not entitled.

  Examples include:
  ➢ Medicare payment for non-covered services;
  ➢ Medicare payment in excess of the allowable amount;
  ➢ Errors and non-reimbursable expenditure in cost reports;
  ➢ Duplicate payments; and
  ➢ Receipt of Medicare payment when another payor had the primary responsibility.
“Simple” Overpayments

- A person has **identified** an overpayment if the provider has **actual** knowledge of the existence of the overpayment or acts in “reckless disregard or deliberate ignorance” of the overpayment.

- Provider may receive information creating an **obligation** to make a **reasonable inquiry**. If the reasonable inquiry reveals an overpayment provider has 60 days to report.

- Failure to make a reasonable inquiry “with all deliberate speed” could result in liability.

“Simple” Overpayments

- “**Identified**” includes Provider:
  - Recognizing up-coding resulting in increased reimbursement;
  - Failure to make a reasonable inquiry into hotline complaint;
  - Learning that Resident died prior to service date on a claim;
  - Learning that services were provided by unlicensed or excluded individual;
“Simple” Overpayments

“Identified” continued:

- Provider performs an internal audit and discovers that an overpayment exists;

- Provider is informed by a government agency of an audit that discovered a potential overpayment and the provider failed to make a reasonable inquiry;

- Provider experiences a significant increase in Medicare revenue for no apparent reason and fails to make reasonable inquiry.

“Simple” Overpayments

“Applicable Reconciliation”

- According to CMS this provision only applies where reconciliation is relevant to a determination of whether an actual overpayment exists.

- Under the Notice of Proposed Rulemaking CMS has stated that it intends to limit this provision to outlier reconciliation and updated SSI ratio information.
“Simple” Overpayments

- Reporting and Refunding:
  - Matters exclusively involving overpayments or errors that do not suggest that violations of law have occurred should be brought directly to the attention of the entity that process claims and issues payment.
  - The existing voluntary refund process will be used.
  - Report will be made to the MAC using available form.

- Information Provided to the MAC will include:
  - How the error was discovered;
  - A description of the corrective action plan;
  - Reason for the refund;
  - Whether Provider has a CIA with OIG or is under the OIG Self Disclosure Protocol;
  - Timeframe and total amount of refund;
  - Medicare Claim Control Number;
  - NPI Number; and,
  - Explanation of statistical sample used (if any).
“Simple” Overpayments

Unanswered Questions:

- When is an overpayment identified?
- What to do where provider cannot quantify the amount within 60 days?
- Downstream providers?
- How far back do you go in calculating the overpayment?
- Is administrative finality available as a defense?
- May provider use the existing adjustment billing process to resolve overpayments within the 1 year window?
- When will regulatory guidance be issued and in what form?

Civil Monetary Penalty and Exclusion Liability

- 42 USC Section 1320a-7a
- Prohibited Conduct
  - False or Fraudulent Claims
  - Violations of the Anti-Kickback Statute (AKS)
  - Violation of Stark
  - Violations of EMTALA
  - Services Provided by Excluded Entity or Individuals
  - Providing Unnecessary Items or Services
Civil Monetary Penalty and Exclusion Liability

Enforcement:
- Civil Monetary penalties based upon claims submitted.
- Exclusion
  - Mandatory Exclusion.
    - Conviction for offenses related to delivery of items or services under Medicare or Medicaid, or patient neglect or abuse.
    - Convictions for certain other felonies.
  - Permissive Exclusion.
    - Misdemeanor convictions for certain offenses.
    - Licensure Actions.
    - False Claims or kickback violations.

Reporting:
- Provider Self-Disclosure Protocol.
  - Federal Register Vol. 63, No. 210, P. 58399 (Friday October 30, 1998)
  - "The Provider Self-Disclosure Protocol is intended to facilitate the resolution of only matters that, in the providers reasonable assessment, are potentially violative of Federal criminal, civil, or administrative laws."
  - The Providers initial decision of where to refer a matter involving non-compliance with program requirements should be made carefully.
  - Discovery of “on-going” fraud should not follow the protocol.
False Claims Act

- 31 USC Sec. 3729
- Prohibitions include knowingly:
  - Presenting or causing the presentment of a false claim to federal government;
  - Making, using, or causing to be made or used a false statement material to an obligation to pay money;
  - Concealing or improperly avoiding/decreasing an obligation to pay the government.
- Requires actual knowledge, deliberate indifference, or reckless disregard.

When to Consider Self Disclosure Options

- 60 day reporting and repayment requirement triggered.

- More than mere repayment may be advisable when:
  - Evidence of knowing/intentional misconduct
  - Pattern of false/inaccurate claims.
  - Likelihood of whistleblower activity.
Self Disclosure Options

- Benefits:
  - Opportunity to frame the issue
  - Greater control over the process
  - Reduces financial exposure
  - Reduces criminal liability
  - Potential False Claims Act (FCA) release

- Risks:
  - Unpredictability

Self Disclosure Options

- Report and Repay to the Medicare Administrative Contractor (MAC)
- HHS-OIG Self Disclosure Protocol
- Department of Justice
- U.S. Attorney
- State Medicaid Department or Medicare Fraud Control Unit (MFCU)
## Contact Information

<table>
<thead>
<tr>
<th>Name</th>
<th>Title and Details</th>
<th>Phone Number</th>
<th>Email Address</th>
</tr>
</thead>
<tbody>
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## Questions

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